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PRINCIPAL INVESTIGATOR: Heidi Flori, MD, FAAP

CONTRACTING ORGANIZATION: Children's Hospital & Research Center Oakland Oakland, CA 94609

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14. ABSTRACT

The overarching goal of this application has been to develop and test the efficacy of a comprehensive, inter-facility transport system that maximizes clinical decision support (CDS) opportunities available to the transport team. This system embodies both the visual and auditory interface available through telemedical infrastructure combined with a real-time, hand held, electronic medical record (EMR) compatible and interactive clinical decision support (CDS) tool. To complete this goal, we have successfully engaged our existing ground and air critical care transport (REACH Air Medical, Inc) infrastructure as well as our Offsite Care critical care telemedicine platform and Children's Hospital Information Technology specialists. Key consultants have included CAPT. Jon Woods, MD. And Comm. Emory Frye MD, US Navy Search and Rescue personnel from San Diego, emotive, Inc., specialty software technologists, and Vidyo, Inc., HIPPA compliant video interface technology. By combining this array of resources, we have created and implemented a more efficient strategy of communication with prehospital and transport personnel. The ultimate goal is to provided more exact and timely interventions minimize transport time to our receiving facility and improve the morbidity and mortality of our transported critically ill pediatric patients. Importantly, this system has the capacity to be developed further to enable more interactive clinical decision support strategies, interface with voice activated charting systems, such as the Dept. of Defense Starix system, and can be ported to other transport teams, both civilian and military.

15. SUBJECT TERMS- clinical decision support, electronic health record, pediatric critical care, transport medicine

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Introduction

Many medical emergencies, such as overwhelming infection, traumatic brain injury and stroke, result in better patient outcomes (including improved chance of survival) with time-sensitive initial patient management. These conditions can occur whether you are an adult or a child. Unfortunately, the American Academy of Pediatrics and American College of Emergency Physicians estimate that only 6% of hospitals have "essential" pediatric supplies for pediatric emergencies. Importantly, many pediatric specific interventions, such as fluid and blood product resuscitation, antibiotic and osmotherapy administration and seizure prophylaxis, are often NOT technically sophisticated and can easily be implemented by non-specialized medical personnel if transport personnel have easy access to clinical decision support (CDS) technology with appropriate time-management prompts. Improperly managed, however, the clinical outcome for the patient can include secondary injuries and even death.

Transport clinicians, particularly those responding to trauma or disaster calls, must be competent to initiate care in both adults and children with a wide array of prior medical problems. Although educational materials may be at hand to the transport clinician while they are "en route" to the sending facility, these references are very rudimentary and less useful once care of the patient has been assumed. The transport environment can be **physically harsh** for the patient, transport personnel and equipment. Once transport to the receiving facility is underway, communication to the receiving hospital is often impractical and/or technically infeasible. Care during transport must continue, however, given that transport is inherently also subject to unforeseen delays due to weather, traffic or other mechanical problems.

Discomfort on the part of an unspecialized transport team and/or lack of appropriate equipment to manage patients of smaller size, particularly children, can and has proven to be a substantial challenge during evacuation from mass casualty incidents, such as occurred after Hurricane Katrina. This is not surprising given that, per a 2003 Institute of Medicine report, "initial efforts at disaster planning did not incorporate the needs of children." The situation in the military venue is further challenged in that pediatric subspecialists, such as pediatric intensive care and neurosurgical specialists, are not available in the Role 1 or 2 environments, yet critically ill and injured children, frequently with penetrating injuries and acute neurosurgical needs, are often seen in those venues. Recent data reported by Spinella et al. and Burnett et al each indicate that in-hospital mortality for pediatric patients admitted to US Army military hospitals in Iraq and Afghanistan is higher than that for adult coalition and non-coalition patients.

The overarching goal of this application has been to develop and test the efficacy of a comprehensive, interfacility transport system that maximizes clinical decision support (CDS) opportunities available to the transport team. This system embodies the visual interface available through telemedical infrastructure combined with a real-time, hand held, electronic medical record (EMR) compatible and interactive clinical decision support (CDS) tool.

Body

Hypothesis:

Our <u>primary hypothesis</u> is that the application of an interfacility telemedical infrastructure that combines an EMR-compatible, clinical decision support application on a handheld device, combined with a visual interface, will lead to greater satisfaction, better compliance with best practice recommendations, more accurate diagnoses, decreased adverse events, and better patient outcomes.

Technical Objectives:

Objective/Task 1: To create and test a <u>portable, robust, interactive and hand-held</u> <u>application</u> to allow time-sensitive CDS algorithms to be used in the transport of critically ill children and adolescents from remote hospital locations to our tertiary care facility.

Subtask 1a: Will the use of the <u>pediatric septic shock CDS algorithm</u> developed and implemented in our prior CHIPERS grant on both ground and air interfacility transport improve compliance with Surviving Sepsis campaign algorithms and decrease end organ dysfunction in children and adolescents with severe sepsis and septic shock?

Subtask 1b: Will the use of the CHRCO <u>pediatric trauma guidelines</u> on both ground and air interfacility transport enable more timely and appropriate medical management of children and adolescents with severe traumatic brain and other multi-organ system injuries?

Subtask 1c: Will the use of the CHRCO <u>pediatric diabetic ketoacidosis</u> (DKA) CDS algorithm on both ground and air interfacility transport improve compliance with time-sensitive management goals of children and adolescents with DKA, a life-threatening manifestation of diabetes that comprises over 10% of all pediatric transports to CHRCO PICU?

Objective/Task 2: To create and test the added utility of a <u>portable yet high-fidelity visual interface</u> in the management and triage of critically ill children and adolescents at the start of ground and air interfacility transports.

Subtask 2a: Will the use of a high-fidelity visual interface on ground and air interfacility transport of critically ill children and adolescents improve the delivery of care by medical transport personnel, as measured by decreased adverse events on transport and improved transport personnel confidence?

Subtask 2b: Will the use of a high-fidelity visual interface on ground and air interfacility transport improve the accuracy of diagnosis and appropriateness of triage for critically ill children and adolescents?

Study Design:

This is a prospective comparison of the management, efficiency and triage of critically ill children and adolescents before and after the implementation of a new ground and air transport electronic clinical decision support system with an interactive visual interface.

Problems Encountered:

Problems encountered in **year 1** included a) major personnel shifts related to the CHRCO EPIC Electronic Health Care Record transition, b) need to outsource software creation and encrypted video connection needs to outside vendors, c) delayed receipt of USAMRMC OPR HRPO approvals.

Fortunately, **year 2** of study has largely been successful on all accounts with our prototyped hard-and software implemented on all transports to the PICU completed by the three primary REACH transport teams serving CHRCO (Santa Rosa, Concord, Stockton). The primary problem encountered this past year has been the need to transition our specialty software needs a third time from Digital Inc. to emotive, Inc. The transition occurred swiftly, however, and through aggressive work with emotive, we have been able to "go-live" with our transport CDS prototype as of April, 2013. This has allowed for 6 months of prototyped equipment use before the final analysis reported herein. Smaller concerns related to video connectivity at sending facilities, relatively short (< 1 hour) transport times and transfer of most patients with traumatic brain injury to the CHRCO Emergency Department rather than the Pediatric Intensive Care Unit have had some impact on our subgroup analyses, but have not impeded the primary research and development process proposed in this application. Details will be described in the sections to follow.

Accomplishments according to proposed tasks:

Our "team" has included all CHRCO based physician and nurse investigators as well as members from CHRCO Information Technology, Mr. Jeff Dunbar, CEO of Offsite Care Telemedical Consultation Co., Dr. Gary McCalla, REACH Air Mediplane Medical Director, and CAPT Jon Woods, MD (military consultant) to assist and guide plans and progress of the handheld equipment development.

In year 1, we also enlisted members of the <u>Starix Technology Think-a-Move</u> personnel on the success and applicability of their speech recognition system as it may ultimately integrate with the platform we are currently developing. In addition, Dr. Flori had lengthy discussions with <u>Comm. Emory Frye</u> from San Diego Naval Hospital before his transition to the civilian sector to discuss and learn from his decision support research in the integrated medical "suitcase" and closed loop mechanical ventilator feedback systems.

In year 2, we expanded our consultative team to include members of the US Naval Search and Rescue staff in San Diego. We had 2 visits with this team, the first in December 2012 and the second in July 2013. Details of their review of the equipment are compiled in sections to follow.

Hardware: The REACH transport personnel were asked to try multiple handheld devices, including the Samsung Galaxy, Dell Latitude, iPAD and iPAD-mini. Ultimately, the teams chose iPAD and iPAD mini to start the go-live period. Each team member was asked to trial both sizes of equipment to determine optimal preference. Final analysis has indicated that the iPAD-mini is the preferred interface for use on transport. Each REACH site (1, 2 and 3) now has access to 2 iPAD-minis for use in transport.

Each iPAD and iPAD-mini have been "ruggedized" with either Otterbox cases or Lifeproof cases. Transport teams have indicated success with both cases from an interface standpoint and from a physical tolerance perspective. No hardware has required replacement as a result of physical damage on transport.

The following is a detailed description of the year 1 and 2 accomplishments according to specific objective and task. Note that for each of the components of the clinical decision support hard- and software requirements (use of hardware, use of clinical decision support algorithms, use of HIPAA compliant video interface, use of point of care laboratory testing equipment and use of patient care report form) REACH transport personnel and PICU faculty and fellows (ie those clinicians directing the CHRCO transport command center) have demonstrated and documented competencies. These competencies are on file with the study primary investigator, Dr. Flori, at CHRCO.

Objective/Task 1: To create and test a portable, robust, interactive and hand-held application to allow time-sensitive CDS algorithms to be used in the transport of critically ill children and adolescents from remote hospital locations to our tertiary care facility.

Year 1 focused on **Phase 1 research and development** of our clinical decision support (CDS) device with particular regard to a) development and refinement of our concept protocol treatment algorithms and b) <u>assessment of existing technology options</u> in relationship to transport "needs" and "constraints" with particular regard for size, weight and durability of equipment (i.e., temperature, water and physical impact resistance).

Year 2 focused on translation of year 1 "background" work into **Phase 2** - implementation of a working prototype for use on patient transport. This has been resoundingly successful and we have had working clinical decision support algorithms, HIPAA compliant, encrypted video connectivity and point of care testing hardware available for all transports to the CHRCO PICU since April 2013. Through the assistance of legal counsel from the Children's Hospital Oakland Research Institute, patent applications are nearing completion.

In year 1, the <u>treatment algorithms</u> for our three concept protocols in Subtasks 1a, b and c (severe sepsis, traumatic brain injury and diabetic ketoacidosis) were created, edited and verified both by the clinician intensivist investigators (Flori and Cvijanovich) and by end user investigators at REACH Mediplane (Dr. Gary McCalla and others). These algorithms a were converted by Drs. Flori and Cvijanovich into "goto" meeting lectures to assist in educating the REACH transport clinician team.

In year 2, these algorithms have been converted to a mobile, clinical decision support tool with a swipe-based user interface format and timer features that monitor both elapsed transport time and time to next protocol-specific interventions. The algorithms accept input based on static features such as age and weight but do NOT accept input based on dynamic factors such as vital sign changes on the patient care monitor or laboratory results appearing from the point of care testing platform. Appendix 1a through 1i show screen shots from each of the 3 concept protocols.

Subtasks 1a, 1b and 1c:

To test the impact of clinical decision support algorithm use on patient care, for each of the concept protocol diagnoses, we randomly selected 5 patients transported to CHRCO prior to the implementation of the clinical decision support tools and compared them to 5, agematched patients transported to CHRCO after the implementation of CDS.

It is important to note that the average flight time (time transport team departed sending facility and arrived at CHRCO) for all transports by REACH 1, 2 and 3 teams during the evaluable time frame was 55.4 +/- 21.8 minutes. Average "bedside time" (time the transport team was at bedside prior to leaving the sending facility) was also relatively short: 39.8 +/- 27.9 minutes. These short time frames resulted in limited ability to test the clinical impact of the CDS tools being used.

For **subtask 1a** (septic shock), *pre-hoc* algorithm compliance metrics included:

- a) receipt of aggressive fluid resuscitation within the first hour after diagnosis of shock
- b) placement of IV or IO vascular access within 1 hour after the diagnosis of shock
- c) receipt of appropriate antibiotics within 1 hour after the diagnosis of shock
- d) acquisition of point of care laboratory testing within 1 hour after the diagnosis of shock
- e) initiation of vasopressors in fluid refractory shock
- f) initiation of stress steroids in fluid and vasoactive refractory shock patients

The age range of patients in this randomly selected cohort of 10 patients ranged from 8 mos (0.7 yr) to 17.7 years. In all 10 cases, clinical management per stated septic shock guidelines was successfully attained before transfer of the patient to CHRCO. One transport team initiated vasoactive medicines en route to CHRCO per the CDS guidelines that may otherwise not have received this medicine in the pre-CDS period.

The management algorithm for **subtask 1b** (traumatic brain injury) was predicated on system-based management rather than time series management guidelines. Therefore, the only pre-hoc algorithm compliance metric studied for this subgroup was assessment of neurologic status q 15 minutes. Patients in this randomly selected cohort of 10 patients ranged from 2.9 to 16.6 years of age. Four of 5 patients in the pre-CDS time frame (80%) documented the necessary q 15 minute neurological assessments compared to 5/5 (100%) in the post-CDS cohort.

The algorithm used most commonly in the post-CDS time frame was the diabetic ketoacidosis algorithm (**subtask 1c**). Pre-hoc determined algorithm compliance metrics in this cohort included:

- a) placement of one IV prior to transport
- b) placement of second IV prior to transport
- c) point of care blood gas testing at diagnosis of DKA
- d) Q 1 hourly glucose checks
- e) Q 2 hourly point of care blood gas testing once diagnosis of DKA established
- f) Insulin infusion initiated before transport
- g) Neurologic assessment q 15 minutes

Ages of patients in this randomly selected cohort of 10 patients ranged from 3.9 years to 13.6 years old. No patients in the pre-CDS cohort had second IV access established prior to transport, compared to 1/5 (20%) in the post-CDS cohort. Also, in the pre-CDS cohort, 4/5 (80%) had appropriate point of care laboratory testing compared to 5/5 (100%) in the post-CDS cohort. All patients, pre- and post-CDS) received serial glucose measurements and neurologic checks q 15 minutes, per protocol.

Together, these subgroup analyses indicate that the post-CDS phase may have resulted in a small increase in algorithm compliance when compared to age-matched controls in the pre-CDS era. That said, there is great inherent difficulty in generating robust clinical predictor and outcome variables to test the additive impact of these clinical decision support tools, particularly when the transport teams using the CDS tools interface with each patient for approximately 1 hour and when the command center physicians are able to interface with the physician team at the sending facility prior to arrival of the transport teams at their site.

Objective/Task 2: To create and test the added utility of a portable yet high-fidelity visual interface in the management and triage of critically ill children and adolescents at the start of ground and air interfacility transports.

In year 1, we engaged our telemedical consultants at Offsite Care, Inc. to insure that optimal visual interface requirements are being assessed and that federal regulatory requirements are being met. We have also engaged Vidyo, Inc. encryption services to enable secure transmission of visual images from sending facility to our receiving command center.

In year 2, we successfully purchased and installed Vidyo servers in the CHRCO IT department and licenses to enable 2 simultaneous, live, streaming video connections with our transport teams. We also enabled several wireless "hot spots" in the CHRCO PICU to insure constant availability for these video links. Prior to the "go live" use of this hard- and soft-ware by the REACH teams, the primary CHRCO study investigators contacted members of the Emergency Department managerial staff at 48 of our top referring facilities to discuss potential concerns they may have and address any potential connectivity hindrances. **Appendix 2** shows a flyer that was distributed to each of these Emergency Department managers after these initial communications. Despite these conversations, the

number 1 concern raised by the REACH transport teams in using the HIPAA compliant, encrypted video connection was the difficulty in circumventing connectivity "firewalls" at the sending facilities. In response to this, troubleshooting guidelines have been placed in the "notes" section of each of the handheld devices in use by the REACH teams. **Appendix 3** shows some photographs of Dr. Flori communicating from the Transport Command Center at CHRCO with REACH transport personnel standing in front of the transport helicopter at a sending location using the Vidyo interface.

Subtasks 2a and 2b reflect the additive value of the video connection to our handheld CDS tool. After use of this equipment for 6 months, transport personnel subjectively felt that transport times had increased primarily because of the use of the video equipment (see Survey responses below.) To test this, bedside time and flight times were compared between those patients transported by REACH 1, 2 and 3 to CHRCO from September 2012 through March 2013 (pre-CDS period) and April 2013 through mid-October 2013 (post-CDS period). As the transport teams were encouraged to use the video and point of care testing equipment on all transports to CHRCO PICU in the post-CDS time period (not simply transports reflecting the patients with 3 concept protocol diagnoses), all transports in these 2 periods were evaluated.

Interestingly, average bedside time and flight time intervals did increase by approx. 5 minutes in the post-CDS period. Statistically, however, these differences were more robust only for the total flight time rather than the bedside time when using both parametric (t-test) and non-parametric (rank sum) testing, see tables below.

CDS	n	Bedside	Bedside time	Bedside time	Bedside time
group		time	(SD, min)	(median,	(5, 95 centiles,
		(mean, min)	_	min)	min)
Pre-CDS	183	37.1	22.7**	33***	6.2, 79.9
Post-CDS	181	42.6	32.2	34	6.1, 105

^{**} p = 0.06 by t-test

^{***} p = 0.45 by rank-sum test

CDS group	n	Flight time (mean, min)	Flight time (SD, min)	Flight time (median, min)	Flight time (5, 95 centiles, min)
Pre-CDS	182	53.0	20.3 *	50*	25, 95
Post-CDS	173	57.9	23.0 *	55*	26.4, 99.4

p =0.03 by both t-test and rank-sum test

An adverse event analysis was done to insure that use of the CDS equipment did not detract, in any way, from required patient care. Pre-hoc metrics assessed (see Appendix 4) included:

1) hypotension > 2 standard deviations for age on arrival

- 2) requirement for vasoactive medicines during transport
- 3) cardiac arrest during transport or on arrival to the PICU
- 4) dislodgement of vascular access
- 5) requirement for intraosseous line placement during transport or on arrival to the PICU
- 6) esophageal intubation
- 7) right mainstem intubation
- 8) accidental extubation
- 9) desaturation < 85%
- 10) hypothermia < 34 deg C on arrival to PICU
- 11) hyperthermia > 38 deg C on arrival to PICU

During the evaluable time period, 171 transports had complete documentation of potential adverse events. A chi squared analysis of these events in the period before CDS implementation (Sept 2012 through March 2013) compared to events in the period after CDS implementation (April 2013 through mid-October 2013) indicated no statistically significant difference for any of the metrics listed above (p range 0.17 – 0.97)

Additional Objectives/tasks:

- 1) Point of Care blood testing: The execution of our time-sensitive treatment algorithms often requires point of care blood gas and analyte testing currently NOT within scope of practice for most remote emergency room personnel and for many transport clinicians. Accordingly, in year 1, we completed necessary multi-disciplinary discussions and developed methodology to allow the Reach transport clinicians to run their own point of care laboratory testing using the EPOC point of care device (Alere, Inc.). In year 2, all REACH 1, 2 and 3 transport personnel successfully gained certification in running these point of care laboratory results, thus increasing potential for compliance with our time-sensitive management algorithms.
- 2) Documentation: The handheld device is capable of being used for documentation purposes by transport personnel. Transport documents from CHRCO and REACH were reviewed in year 1. In year 2, investigator team created an "interim evaluation" document that includes vital elements for handoff communication to the receiving institution clinical team. This "interim document" is able to be completed in real time and transmitted to the receiving tertiary medical center team in real time as a printed, pdf document. As of this writing, CHRCO has not "gone live" with the EPIC Electronic Health Care record and REACH is actively changing their documentation platform. This has resulted in the Interim Patient Care form available on the handheld device NOT being able to auto-populate the more lengthy REACH case report form, as initially desired; nor is the Interim Patient Care for able to be uploaded by the CHRCO PICU team into the EPIC HER as an appended document at this time. These documentation concerns are likely to be remedied within the next 3-6 months.

Overall performance of the added CDS tools:

In order to ensure that the use of the handheld device and CDS algorithms do not negatively interfere with transport personnel workflow, in year 1, the investigators created an anonymous, web based survey intended for transport personnel. The survey, developed by Dr. Flori and Ms. Silva, has been reviewed by Dr. McCalla and other REACH transport personnel. In year 2, this survey was administered before the start of CDS equipment use and again at the end of study. The results follow:

- a) 42% of respondents participated in *pediatric* transport medicine for 1-5 years with an additional 42% participating for > 5 yrs.
- b) > 92% of respondents used the prototyped CDS equipment during the study period.
- c) 55% indicated that use of the CDS equipment improved their confidence on transport.
- d) 100% indicated that use of the CDS equipment lengthened transport times.
- e) 55% indicated that use of the CDS equipment (all components) improved communication with the transport command physicians
- f) 38% indicated that use of the clinical decision support algorithms resulted in fewer errors (compared to 62% that indicated that use of the algorithms did not change the error rate)
- g) 50% indicated that use of the Vidyo equipment improved patient management compared to 40% that indicated no change in management and 10% that indicated use of the video equipment worsened management
- h) 63% reported improved communication with the command center physician when using the Vidyo equipment.
- i) 100% indicated that ability to do point of care laboratory testing on transport improved transport standard of care.
- j) Suggestions for future development included 1) making the system more user friendly 44% 2) making clinical decision algorithms more interactive (see future directions below 44%), 3) adding more algorithms 22% 4) voice activated documentation 44%

Future Work:

Reporting of results:

- 1) The data reported above is currently being formatted for submission to national and international pediatric critical care research meetings as well as in manuscript form.
- 2) As described above, the primary investigators have been working closely with Children's Hospital Oakland Research Institute legal counsel on patent protection for the clinical decision support "package" for use on medical transport.

Maintenance and local expansion of existing platform:

3) Existing CDS equipment, including the clinical decision support algorithms, Vidyo encrypted video interface, EPOC point of care testing will remain in use for REACH

- 1, 2 and 3 teams to use when transporting children to CHRCO. REACH team 7, based out of Sacramento, is also being in-serviced on the equipment for expansion of these services to their site.
- 4) Within CHRCO, the equipment is being installed in the Emergency Department and the Neonatal Intensive Care Units, thereby expanding the opportunities for use of the CDS equipment on transports returning to those locations as well. Faculty and fellows in those locations are gaining and documenting competency in the equipment usage prior to use.
- 5) All hardware and software have been enabled and warrantied for maintenance needs for the next 18 months so as to facilitate continued use in the existing capacity while additional funding for "next steps" of development can be secured.
- 6) Two additional algorithms, status asthmaticus and status epilepticus, are to "go live" for use on pediatric critical care transport by the end of October. (Appendices 5 and 6)
- 7) Current infrastructure is being maintained to continue to collect data on each transport wherein CDS tools are used, as well as continue assessment of transport times and adverse events. These data will continue to be reported through the CHRCO Transport and Pediatric Intensive Care Continuing Quality Improvement processes.

Broader expansion - Civilian use

8) As described above, the REACH transport teams have great skill in pediatric critical care transport. Further, bedside and transport times are relatively short (< 1 hour) thereby making analysis of the clinical impact of the CDS tools on patient outcomes difficult to ascertain. (This is particularly relevant because many time-sensitive management algorithms describe needed interventions in 1 and 2 hour intervals, with only vital sign changes to be assessed in intervals < 1 hour, the usual transport time.) Therefore, the existing interface may benefit greatly for testing with a) transport personnel with less pediatric critical care experience and/or b) personnel transporting critically ill children over greater distances. To this effect, this past summer, Dr. Flori has initiated contact with Mr. David Duncan, Medical Director of CalStar transport team and Dr. Dani Bowman, head of pediatric telemedicine and transport at the Alaska Native Medical Center (ANMC). Calstar is a critical care and trauma transport team in California. Although established in those venues, Calstar personnel generally have less experience in pediatric age groups than REACH personnel. Alaska Native Medical Center receives critically ill children in transport from all areas of Alaska. Average transport times for these transports is usually in excess of 3 hours per transport. Dr. Flori will continue to collaborate with CalStar and ANMC as potential validation sites in the future.

Broader expansion - Military use

9) As described above, CAPT Jon Woods, MD has been retained as military consultant to this project throughout the 2 years. CAPT Woods enabled the primary investigators to meet with and get feedback from key officers in the US Navy Search

and Rescue division in San Diego. In July, 2013, Dr. Cvijanovich showed the current prototype to CAPT. Andy Bestwick, current SAR model manager and CAPT Mark Kirkland. Both were enthusiastic about the applications overall and saw farreaching utility throughout the military as well as for the sheriff's office, border patrol and search and rescue teams. They indicated that a cache of easily accessible protocols including stroke, myocardial infarction and other adult disease and trauma states would be useful. CAPT Bestwick also indicated interest in deploying devices for use in Guam, Whidby Island, Cherry Point, Norfolk and San Diego to help broaden our experience with the equipment for use in other scenarios and arenas. Another potential area of use would be in training army and navy flight medics, such as at Fort Rucker training school.

Further development of technology:

- 10) The current technology would definitely benefit from continued broadening of the clinical decision support algorithm platform "up and out" to include other, major disease states for both children and adults. These can include, but certainly are not limited to, myocardial infarction, stroke (adult and pediatric), pulmonary embolus (adult and pediatric), burns (adult and pediatric), multi-system trauma (adult and pediatric), acute respiratory failure (adult and pediatric), sedation (adult and pediatric), etc.
- 11) The current grant application created a "passive" CDS system wherein the transport clinician can "scroll" the medical application in real time before and during the transport. Ultimately, the goal is to create an "active" CDS system. One example previously described is wherein the transport personnel can "link" to other decision algorithms (i.e., transport personnel use sepsis algorithm and find the patient to be in respiratory distress. Algorithm can "link" to respiratory distress algorithm.) Another example involves streaming patient data into the CDS algorithm such that the algorithm can prompt the clinician when certain patient vital sign parameters or laboratory results are out of a desired range.

The current grant application does not include this level of "interactivity" in its scope and would require additional grant funding sources, development time and expanded computer software expertise to complete. Accordingly, we have been seeking our "next opportunities" to carry our project forward.

Key Research Accomplishments

1) Comprehensive clinical decision support tools developed and implemented on patient care transport including hardware with ruggedized casing, clinical decision support algorithms, HIPAA compliant encrypted video conferencing, point of care laboratory testing with all equipment "users" documenting competency in use of same with ability to maintain current level of use for next 18 months as additional funding is obtained.

- 2) Implemented clinical decision support tools in our 3 concept protocol areas of severe sepsis/septic shock (**Appendix 1 d, e, f**), traumatic brain injury (**Appendix 1 g, h, i**) and diabetic ketoacidosis (**Appendix 1a, b, c**).
- 3) Completion of analysis of adverse events, transport times and targeted subgroup analyses.
- 4) Completion of comprehensive survey of REACH transport personnel on all aspects of CDS tools implemented to date.
- 5) Initiation of patent documents.
- 6) Imminent expansion of existing CDS tools to CHRCO Emergency Departments and Neonatal Intensive Care Units.
- 7) Imminent expansion of CDS algorithms to include 2 additional algorithms (status asthmaticus and status epilepticus, **Appendices 5 and 6**).
- 8) Plans for validation testing to other transport teams (CALSTAR), other areas of the country (Alaska Native Medical Center) for civilian use and other areas of military use (see above).

Reportable Outcomes

Patent application nearing completion (copy available upon request).

Conclusions:

Recent evidence suggests that the original benefit of the "scoop and run" or "golden hour" concept of transport no longer applies, particularly for those patients with medical emergencies such as septic shock, traumatic brain injury or stroke. Although expeditious management at the sending facility is still warranted, there is mounting evidence that aggressive treatment of adults and children in the field and en route, often with technically unsophisticated strategies like temperature control, fluid resuscitation and blood pressure management, can improve clinical outcomes.

Specialized transport teams may also improve outcomes particularly for neonatal and pediatric patients but they are costly and not always available, such as during trauma or disaster scenarios. Targeted and timely clinical decision support, whether by electronic and/or visual interface with clinicians at the receiving institution transport command center, may help transport personnel hone medical management further, resulting in improved patient morbidity and mortality. On the other hand, the thoughtless and inelegant application of technology that needlessly lengthens transport times and/or results in poor communication has the potential to interrupt the otherwise organized flow of transport with negative impact on the patient.

The overarching goal of this application has been to develop and test the efficacy of a comprehensive, interfacility transport system that maximizes clinical decision support (CDS) opportunities available to the transport team. We have been successful in this endeavor to date. Our prototyped system embodies both the visual and auditory interface

available through telemedical infrastructure combined with a real-time, hand held, electronic medical record (EMR)- compatible and interactive clinical decision support (CDS) tools for 5 common pediatric critical care disease states. To complete this goal, we have successfully engaged our existing ground and air critical care transport (REACH Air Medical, Inc) infrastructure, our OffSite Care critical care telemedicine platform and Children's Hospital and Research Center Oakland (CHRCO) Information Technology specialists, and key consultants in the military, CAPT. Jon Woods, MD, and Comm Emory Frye MD, and have contracted services from emotive, computerized medical software technologists and Vidyo, Inc, encrypted video interface systems.

By combining this array of resources, we have implemented new and promising communication with pre-hospital and transport personnel. Our preliminary data support that the effects are positive with transport team members reliably reporting improved communications with the command center physicians and increased ability to manage patients with time-sensitive management needs. Conversations with others in both military and civilian transport venues indicate that this equipment can be broadly applied to these other venues as well. With continued use, our ultimate goal is to provide more exact and timely interventions, minimizing transport time to our receiving facility and therefore improving the morbidity and mortality of all transported critically ill adult and pediatric patients. As the CDS currently in use is still essentially "passive" in nature, we must continue to develop improvements beyond the scope of this grant.

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Appendices:

Appendices 1 a - i Screen shots from clinical decision support algorithms for sepsis,

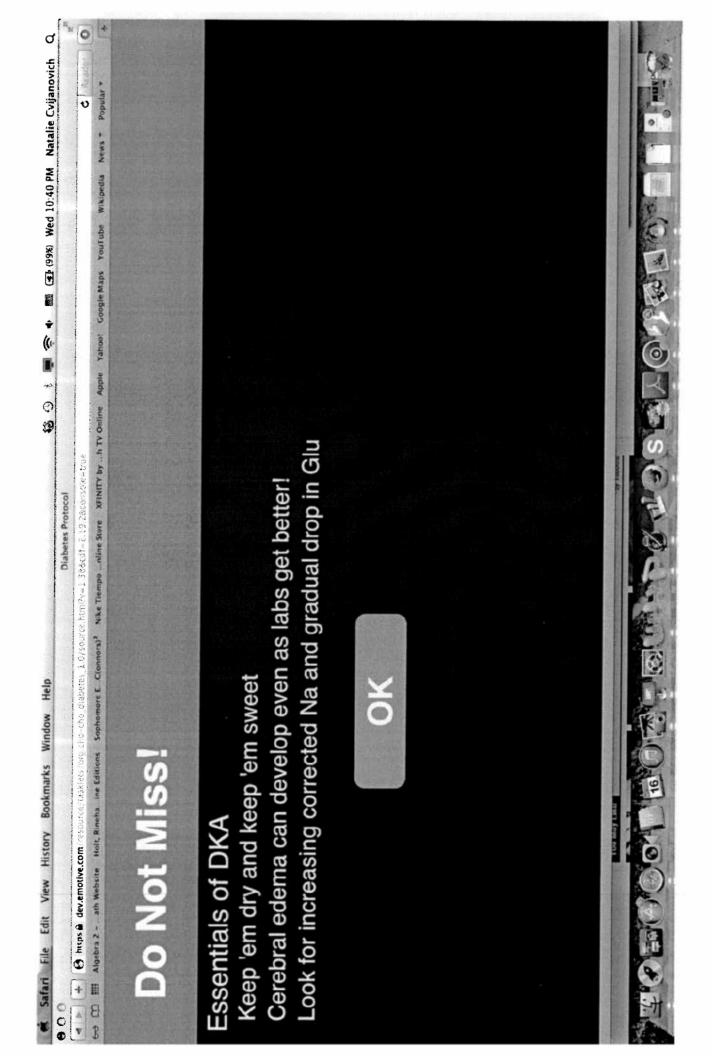
traumatic brain injury and diabetic ketoacidosis

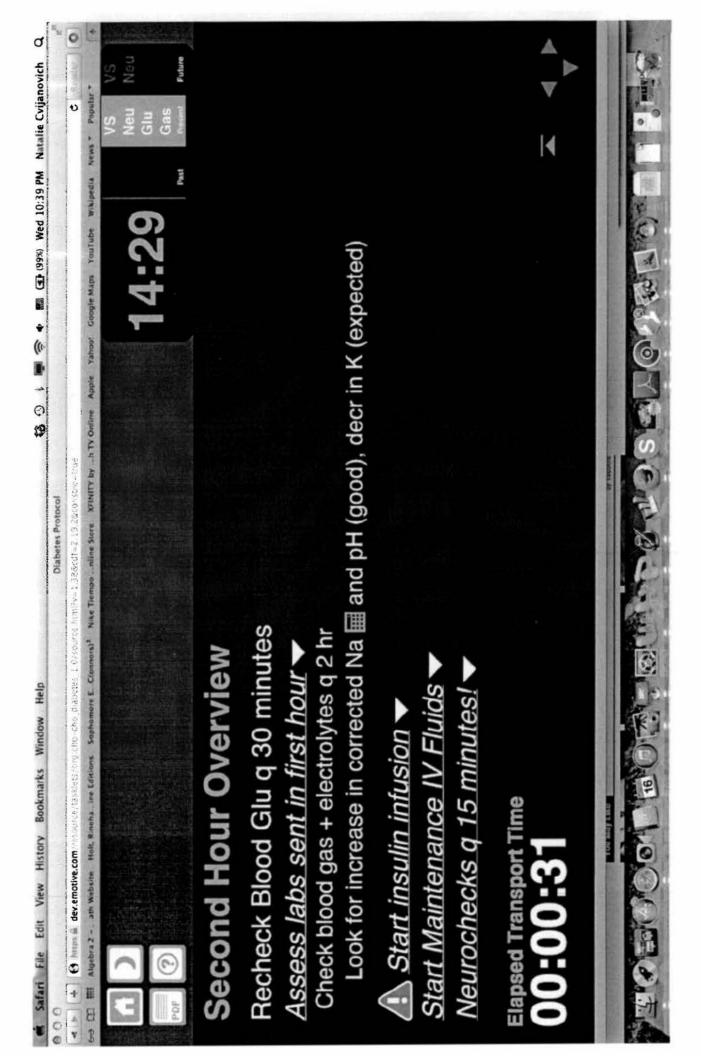
Appendix 2: Transport Clinical Decision Support Flyer to Sending facilities
Appendix 3: Photographs of Video Communication between Command Center

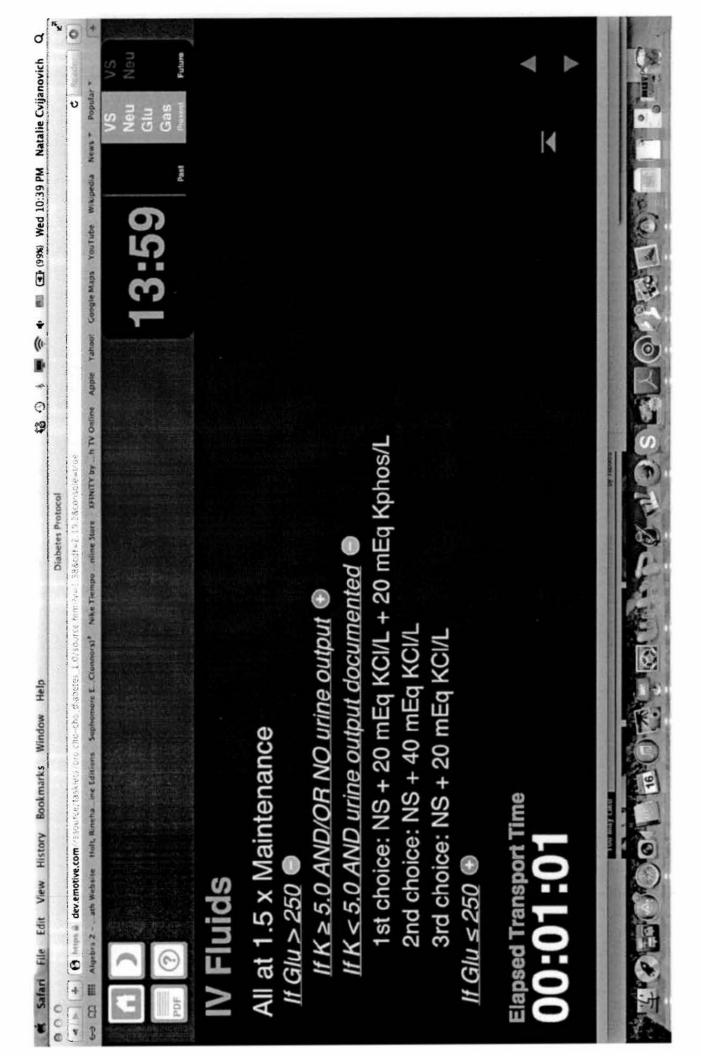
physician and transport personnel

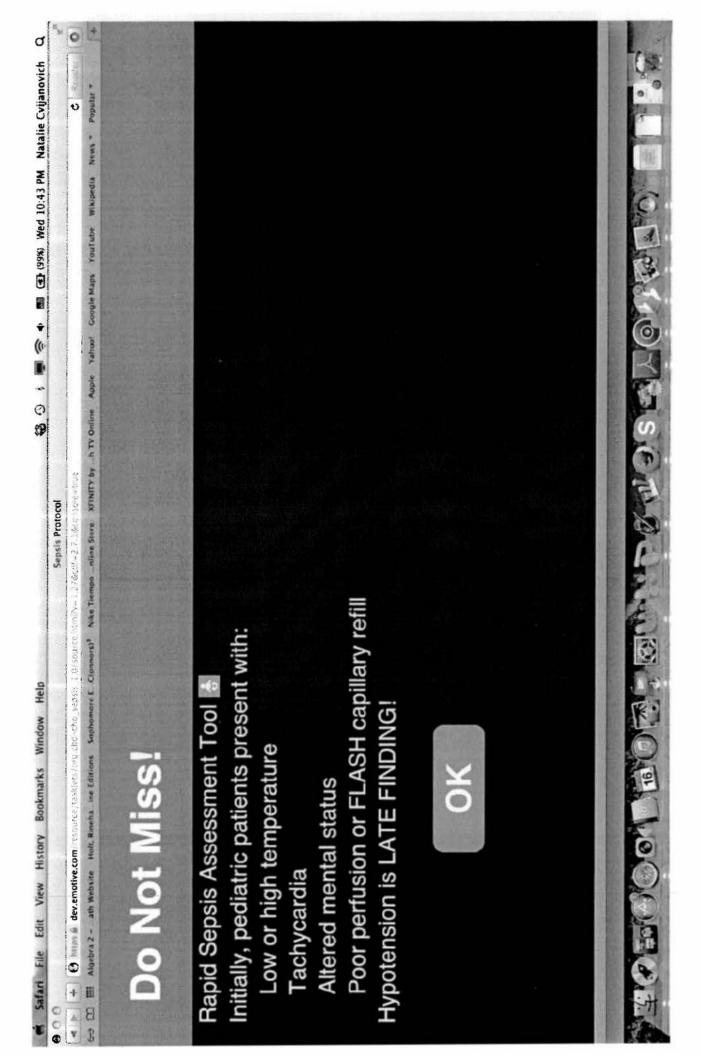
Appendix 4: Adverse Event Form

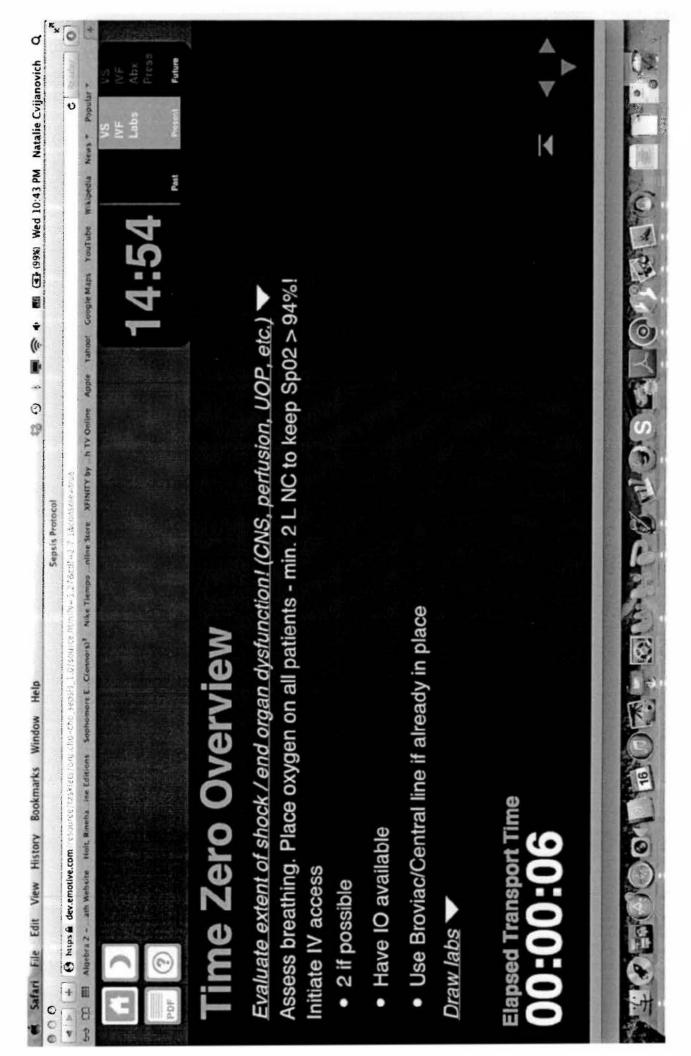
Appendix 5: Status Asthmaticus Clinical Practice Guideline Appendix 6: Status Epilepticus Clinical Practice Guideline

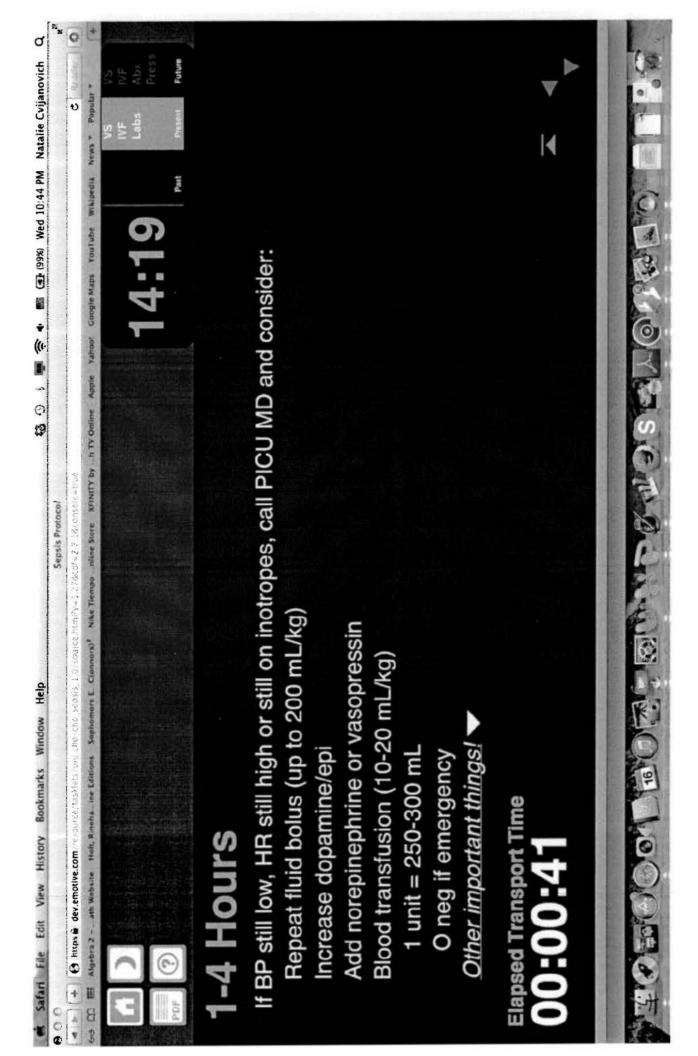


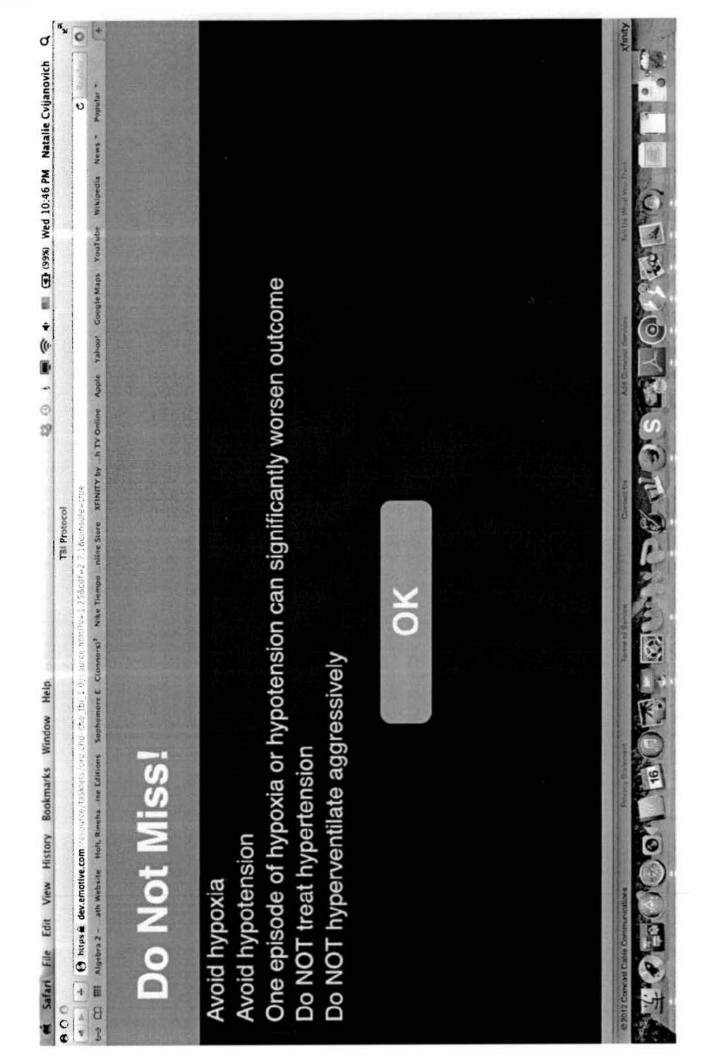


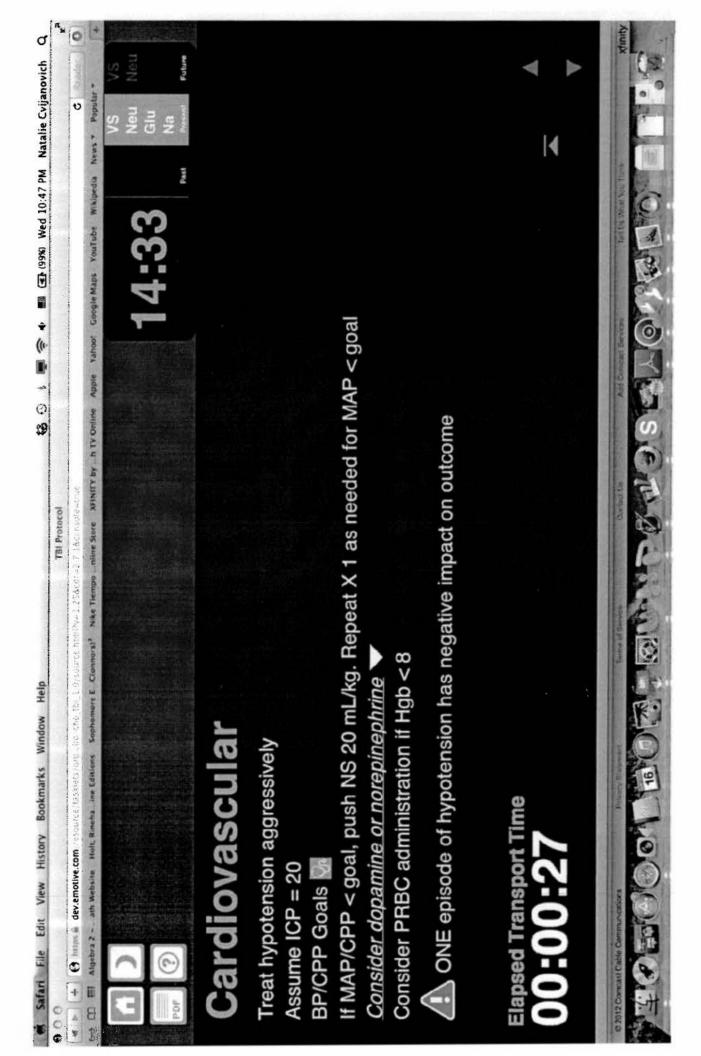


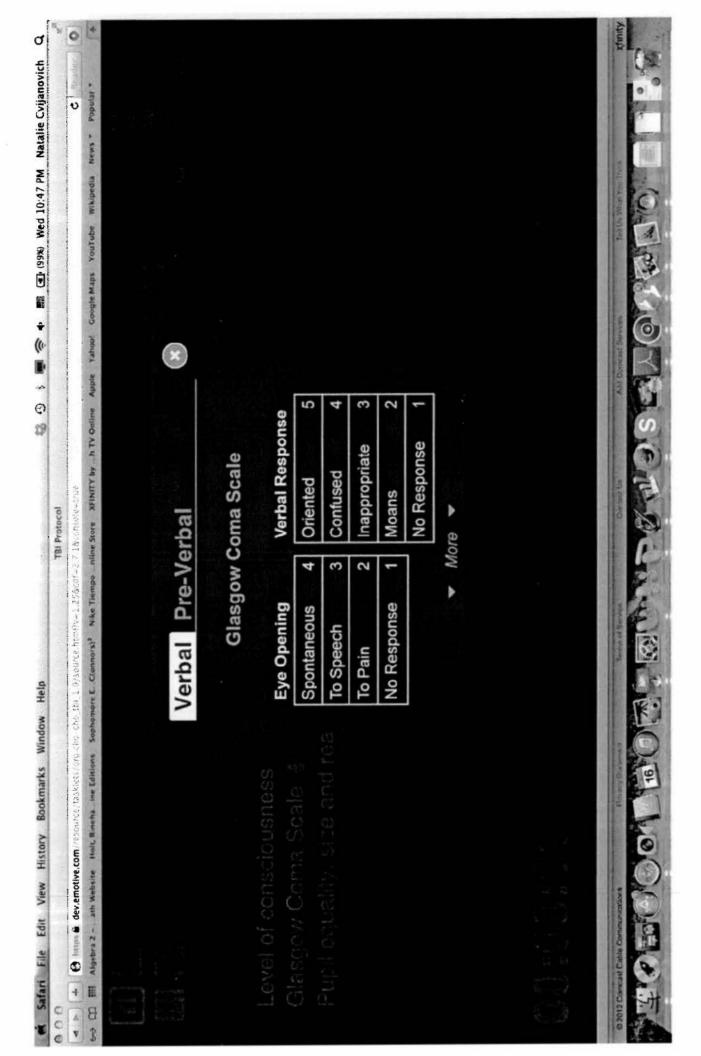
















Advanced Clinical Decision Support for Transport of the Critically III Pediatric Patient

Who: REACH transport teams will be utilizing a device, application and video/voice interface with CHRCO PICU patients

When: Go live starting early April

Where: All hospitals transporting patients to CHRCO through REACH.

Why: To improve the quality of care and communication when transporting critically ill pediatric patients.

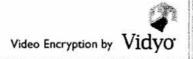
How: Developed by CHRCO through a grant provided by the Department of Defense Telemedicine and Advanced Technology Research Program. Award. No.W81XWH1110523

What: A device (iPad or iPad mini) with application that includes algorithms for the care of pediatric patients with the diagnosis of sepsis, DKA and traumatic brain injury (more to come). Also, enables the Reach transport team to utilize HIPAA compliant video and voice interface to communicate with the CHRCO intensive care team.

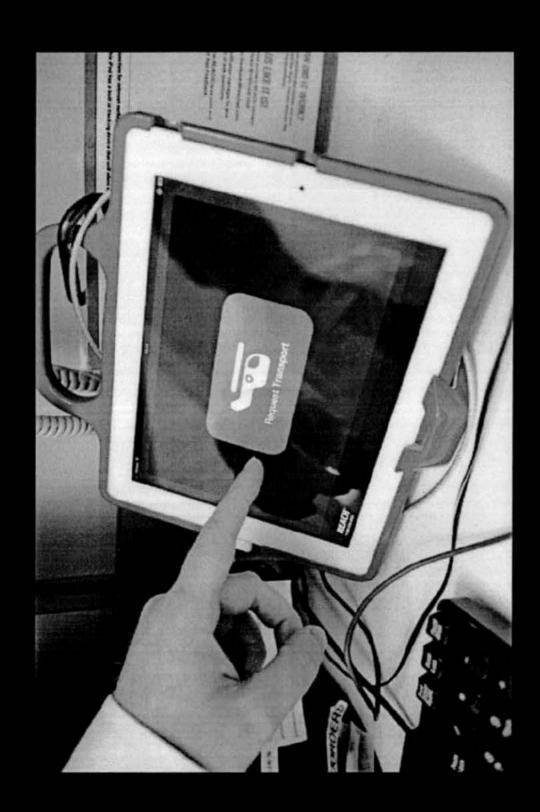
For more information contact:

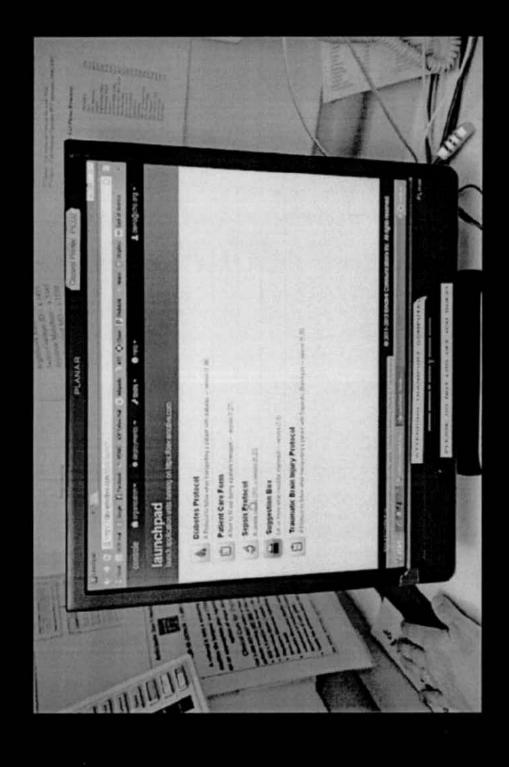
Erin Silva ersilva@mail.cho.org
Heidi Flori hflori@mail.cho.org
Natalie Cvijanovich
ncvijanovich@mail.cho.org
Gary McCalla gary_mccalla@reachair.com

Children's Hospital Oakland Transfer Center I-855-CHO-KIDS



















TRANSPORT: PICU RECEIVING

Addressograph

or

Date:	Label				
Diagnosis upon arrival:					
Hemodynamic compro	mise				
[] YES [] NO	Hypotension < 2 SD for age on arrival (see belo	<u>w</u>)			
[] YES [] NO	Requirement for initiation of vasoactive medica	ations during transport			
[] YES [] NO	Cardiac arrest during transport or on arrival to	PICU			
Vascular access					
[] YES [] NO	Dislodgement of vascular access (PIV, central o	r arterial)			
[] YES [] NO	Requirement for intraosseous line placement either during transport or upon immediate arrival to the PICU				
Airway events					
[] YES [] NO	Esophageal intubation				
[] YES [] NO	Right mainstem intubation				
[] YES [] NO	Accidental extubation				
[] YES [] NO	Significant desaturation (<85%)				
[] YES [] NO	Requirement for reintubation on arrival to the	PICU			

Thermal event on arrival to PICU

[] YES	[] NO	Hypothermia (temp < 34 degrees C)
[] YES	[] NO	Hyperthermia (temp > 38 degrees C)

COMMENTS:	***************************************	***************************************	

AGE GROUP	SYSTOLIC BP
0 - 28 days	<60 mm Hg
1 - 12 months	<70 mm Hg
1 - 10 years	<70 mm Hg +
	(2x age in years)
>10 years	<90 mm Hg

Print Name:	:	Signature:	

Asthma Exacerbation Assessment

Do Not Miss:

- a) Decreased or absent breath sounds, bradypnea and/or bradycardia seen with impending respiratory failure
- b) Extreme agitation commonly seen with severe hypoxemia OR obtundation with severe hypoxemia
- c) Tachycardia IS expected. Minimal risk of myocardial infarction with beta agonist use compared to adults
- d) Allow patient to assume position of comfort (usually tripod NOT supine) to allow for accessory muscle usage

Initial Assessment:

Focused history

Duration of symptoms

Preceding illness

Trigger

Current home treatment/ home meds and effectiveness

Past history

Known asthma

Medication/ compliance

Number of prior admissions

Prior intubation or ICU admission

Note: History of intubation or ICU admission is indicator of asthma severity and increased risk of mortality

Focused physical exam

Vital signs

Note: Slow RR can be ominous sign

Work of breathing, aeration, wheezing (Inspiratory and/ or Expiratory)

Speech (Full sentences, short phrases, single words)

Mental status

Labs/Xrays

Clinical exam overrides labs

Blood gas is NOT required for assessment

Note: Attempts at obtaining blood gas can exacerbate distress without improving assessment

Note: "Normal" pCO2 with tachypnea is concerning

CXR: Consider antibiotics if infiltrate on CXR

Ceftriaxone 50 mg/kg IV

MILD DISTRESS

- · Shortness of breath with activity
- Able to lie flat
- Speaks in complete sentences
- Normal mental status
- Stranger anxiety
- Moderate wheezing, mostly expiratory
- HR usually WNL for age <link to HR chart>

IF YES = START MILD < link to MILD>
IF NO = GO TO MODERATE < link to MODERATE>

MODERATE DISTRESS

Infants:

- Softer, shorter cry
- Difficulty feeding
- ↑RR <link to RR chart>
- Accessory muscle use
- Inspiratory/expiratory wheezes

Children /Adolescents:

- Prefer sitting upright
- Short phrases, one word answers
- Inspiratory/expiratory wheezes

IF YES = START MODERATE < link to MODERATE > IF NO = GO TO SEVERE < link to SEVERE DISTRESS >

SEVERE DISTRESS/IMPENDING RESPIRATORY FAILURE

- Restlessness/agitation, or lethargy
- Severe retractions
- Head bobbing
- · Absent or minimal wheezes
- Bradypnea
- Unable to speak

IF YES = START SEVERE < link to SEVERE>

MILD

- Give oxygen to achieve SpO₂ ≥ 92%
 - a) Nasal cannula O2 @ 1-3 LPM
 - b) Simple mask @ 6 LPM minimum
- 2) Inhaled short acting β-agonist
 - < 30 kg: 2.5 mg aerosolized albuterol
 - > 30 kg: 5 mg aerosolized albuterol

May repeat up to 3 times in 1 hour

CONSIDER levalbuterol (Xopenex) 0.15 mg/kg (max dose 5 mg) nebulized if strong parental preference

- 3) Oral systemic steroids
 - a) 1 mg/kg Prednisone po (max 60 mg) OR
- b) Dexamethasone 0.6 mg/kg po (max 10 mg)
- 4) If no improvement in WOB or distress go to MODERATE

MODERATE

1) Place PIV. If unsuccessful on first attempt may repeat x 2.

NOTE: Excessive stimulation can cause deterioration in respiratory status. Re-examine patient after IV placement and consider IM or SQ medication instead of repeated attempts. Have IO available for rapid deterioration

- 2) Oxygen to keep $SpO_2 \ge 92\%$
- 3) High dose inhaled albuterol:

START WITH:

If < 30 kg, give 2.5 mg aerosolized albuterol q 10 min x 3 If \geq 30 kg, give 5 mg aerosolized albuterol q 10 min x 3

THEN consider: Continuous albuterol link to albuterol recipe>

If < 10 kg , then 10 mg/hr If 10-20 kg, then 15 mg/hr If > 20 kg, then 20 mg/hr

- 4) Prefer IV corticosteroids
 - a. Methylprednisolone 1 mg/kg IV (max 125 mg) OR
 Dexamethasone 0.6 mg/kg IV (max 10 mg)
 - b. If no IV access, may use Prednisone 2 mg/kg po (max 60 mg) OR Decadron 0.6 mg/kg IM (max 10 mg)

- 5) Ipratropium Bromide (1.5 ml) aerosolized with albuterol
- 6) NS bolus 20 mL/kg IV

May repeat x 1 if perfusion poor

If no improvement in WOB or distress:

ADD

a) Magnesium Sulfate x 1

50 mg/kg (range is 25-100 mg/kg) IV over 20 min (max - 2 grams)

b) Terbutaline - 0.1 mg/kg sq (max - 0.25 mg)

May repeat q 5 min x 3 prn ongoing moderate distress

c) LEAST PREFERRED:

SQ Epinephrine 0.01 mg/kg (max - 0.5 mg)

May repeat q 20 min x 3 prn ongoing moderate distress

NOTE: thigh muscles preferred over arm

If still no improvement in WOB or distress:

START

1) Terbutaline infusion at 1 mcg/kg/min <link to instructions on how to mix terbutaline infusion>

NOTE: Pediatric doses for this drug are MUCH HIGHER than recommended adult doses

2) Assess for **IMPENDING RESPIRATORY FAILURE** < link to "severe distress/impending respiratory failure exam

SEVERE/IMPENDING RESPIRATORY FAILURE

- 1) Support Airway
 - a. 100% Oxygen
 - b. If CPAP/Bi-PAP available
 - i. Titrate to PEEP around 8 cm H₂0
 - ii. PIP 12-18 cms H₂O

*If bradycardic, obtunded or severely hypoxic with 100% oxygen:

- a) Intubate and continue with medication support listed below <place link for intubation drugs chart>
- b) CBG or ABG via EPOC (expect severe hypercarbia)
- c) Expiratory phase for intubated patients may be MANY SECONDS long, so must use LOW SIMV rates (5-15 bpm max).
- d) Expect patient to awaken after paCO2 has normalized. Then, initiate sedation strong consideration for use of ketamine and midazolam. MUST muscle relax if patient begins spontaneous breathing to avoid barotrauma.

- e) If patient has not woken up after 15 minutes of mechanical ventilation, repeat CBG and expect residual hypercarbia
- f) Status asthmaticus patients with respiratory failure often have SEVERE mucous casting inhibiting effective ventilation and oxygenation.
- 2) Continuous albuterol < link to albuterol recipe>

< 10 kg 10 mg/hr 10-20 kg 15 mg/hr > 20 kg 20 mg/hr

- 3) IV corticosteroids
 - a. Methylprednisolone 2 mg/kg (max 125 mg) OR
 - b. Dexamethasone 0.6 mg/kg IV (max 10 mg)

NOTE: If steroids have already been given orally, consider re-dosing IV as above

- 4) Magnesium Sulfate IV x 1 50 mg/kg (range is 25-100 mg/kg) IV over 20 min (max - 2 grams)
- 5) Terbutaline infusion at 1mcg/kg/min < link to instructions on how to mix terbutaline infusion>

May titrate up by 0.5 mcg/kg/min q 30 mins to max of 4 mcg/kg/min NOTE: Pediatric doses for this drug are MUCH HIGHER than recommended adult doses

Charts that can all be linked to....

Guide for range of normal respiratory rules in awake children

Age	Normal Rate		
< 2 mos	< 50/min		
2 mos – 12 months	< 40/min		
1 year – 5 years	< 30/min		
6 years – 8 years	< 20 min		

Guide for range of heart rate in children

Intubation - Preferred Drugs:

- Lidocaine 1mg/kg to prevent laryngospasm
- Ketamine 1mg/kg IV can also give IM repeat q 15 60 minutes
- Midazolam 0.1 mg/kg max 3 mg repeat q 20 -60 minutes
- Rocuronium 1mg/kg repeat q 30-60 minutes
- Vecuronium 0.1 mg/kg repeat q 30 60 minutes

Continuous albuterol recipe

Duration of nebulization (hrs)	Dose (mg/hr)	Liter flow (L/min)	Albuterol (mL)	Normal saline (mL)	Total volume (mL)
4	10	10	8	112	120
4	15	10	12	108	120
4	20	10	16	104	120
8	10	10	16	224	240
8	15	10	24	216	240
8	20	10	32	208	240
4	10	15	8	192	200
4	15	15	12	188	200
4	20	15	16	184	200
8	10	15	16	184	200
8	15	15	24	176	200
8	20	15	32	168	200

Terbutaline recipe

Standard concentration = 1 mg/mL

Each vial = 1 mg/mL

Prepare drip based on amount required for estimated length of transport plus 2 hours

Rate (mL/hr) = (Dose in mcg/kg/min x wt x 0.06)/1 (Standardized concentration)

Sample calculation

Weight = 10 kg

Dose = 2 mcg/kg/min

Therefore,

Rate $(mL/hr) = (2 mcg/kg/min \times 10 kg \times 0.06) / 1 mg/mL = 1.2 mL/hr$

Make up a total volume of (1.2 mL/hr x 4 hr) = 4.8 mL

Pediatric Status Epilepticus Protocol (History of seizures)

Time zero

- 1. Assess, treat, stabilize Airway Breathing Circulation (See Assessment and Standard Care for all Patients protocols).
- 2. Perform and record **neurologic exams** at least **every 5 minutes** (timer q5' with reminder of SpO2 goal and BP goal as well).
 - A. Level of consciousness
 - B. Glasgow Coma Scale (link to GCS, both pediatric and adult)
 - C. Pupil equality, size and reactivity.
 - D. Gaze conjugate or disconjugate
 - E. BP
- 3. Secure airway with ETT if: (link to "Endotracheal intubation, oral")
 - A. Persistent SpO2 < 94% despite optimal non- invasive oxygen supplementation
 - B. Loss of gag reflex
 - C. Any clinical signs of herniation: Cushings= systemic hypertension + bradycardia and irregular respirations
 - D. Avoid paralyzing patient during intubation if clinically feasible to avoid masking seizures
 - a. If chemical paralysis is necessary for pt safety, monitor pt for: hypertension,
 - desaturation and pupil dilation which may be signs of underlying seizure activity.
- Consider head CT if evidence of trauma--Neurosurgical intervention if needed and available resources at existing location

Fluids and electrolytes

- 1. Check blood **glucose** every 30 minutes until seizure stopped. Continue checking every hour for 4 hours once stable
 - A. If >150 mg/dl do not give dextrose-containing fluids. Use NS as maintenance
 - B. If <80 mg/dl give D10W, 2 mL/kg, slow push over 1 min, then use D5NS as maintenance
 - C. If glucose has been treated, repeat fingerstick glucose checks q 15 minutes throughout transport

2. Check Na

- A. If Na < 120 AND 3% NaCl available, give 3% NaCl 6 mL/kg over 10 min. (see 3% NaCl protocol)
- B. If Na < 130 and child is still seizing at any time after first Fosphenytoin load, give 3% NaCl 6 ml/kg IV over 10 min. (see 3% NaCl protocol)
- C. If child requires treatment for hyponatremia, check and treat sodium after each bolus of 3% saline if still hyponatremic
- 3. Check ICa++ (Ionized calcium)
 - A. If ICa++ < 0.90, treat with calcium gluconate 50 mg/kg IV over 2 minutes

Neurologic

- 1. IF seizing,
 - A. lorazepam, 0.1 mg/kg IV slow push over 1 minute, 2 mg max dose
 - B. check blood pressure and respiratory status. Consult MD if BP >150
 - C. repeat lorazepam 0.1 mg/kg IV slow push over 1 minute, 2 mg max dose
- 2. IF still seizing,
 - A. Fosphenytoin or phenytoin 20 mg/kg IV over 20 minutes.
 - B. Wait 5 minutes. Check and correct glucose if initially required treatment
 - C. Fosphenytoin or phenytoin 10 mg/kg
- 3. If still seizing,
 - A. Consider head CT to rule out bleed even if no evidence of trauma
- 4. If still seizing,
 - A. Phenobarbitol 20 mg/kg IV over 20 minutes.
 - B. Check blood pressure. Correct if necessary.
 - C. Check respiratory status. Treat if necessary
 - D. Check glucose if patient had hypoglycemia and sodium if patient had hyponatremia
 - E. Phenobarbitol 10 mg.kg IV over 20 minutes
 - F. Check and treat blood pressure, respiratory status, and glucose/Na as necessary
- 5. If intubated, maintain sedation and analgesia
 - A. Fentanyl 1 mcg/kg or morphine 0.1 mg/kg
 - B. Midazolam 0.1 mg/kg
 - C. Avoid propofol due to risk of hypotension

D. Avoid paralytics if clinically possible

Respiratory

Check respiratory rate and patterns continuously.

A. Goal SpO2 > 94% (ideal-alarm if <940%)

Note: One instance of hypoxia has significant negative impact on outcome. Continuously ensure adequate oxygenation.

- B. Goal EtCO2 35-45mm Hg. (ideal-alarm when EtCO2 <35)
- C. Ventilation strategy for the intubated patient aimed at minimizing mean airway pressure, maximizing oxygenation and maintaining PCO2 within normal limits

Cardiovascular

Maintain BP

A. Age <1, MAP > 50 (ideal-alarm if <50)

- B. Age 1-8 yrs, MAP > 70 (ideal-alarm if <70)
- C. Age ≥8, MAP > 80 (ideal-alarm if <80)
- D. IF MAP < goal, push NS 20 mL/kg. Repeat X 1 as needed for MAP < goal
- E. Consider dopamine (5-10 mcg/kg/min)

Fever

Treat hyperthermia

A. Acetaminophen 15 mg/kg NG or PR

Infection

- A. If infection is suspected, verify whether blood cultures have been sent and LP done.
- B. If LP has been done, try to obtain one CSF tube to take with on transport.
- C. Verify whether antibiotics have been given. If not, consider Ceftriaxone. Call MD for consult.

Positioning

A. Transport pt with HOB elevated 15-30 degrees and head midline to promote venous drainage.

Pre-existing seizure disorder—treated

1. Check levels of any antiepileptics patient should be taking

Supporting Data: none